

### **REMARKS**

Claims 1-9 and 11-28 are pending in the present application. Claims 1-9 and 11-28 have been amended and claim 10 has been canceled. Reconsideration of this application, as amended, is respectfully requested.

#### **Rejection Under 35 U.S.C. §§ 102 and 103**

Claims 1-7, 9, 12-16, 18 and 26 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Hegarty, AU-A-18442/83. Claims 20 and 21 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hegarty. Claims 22, 23 and 27 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hegarty in view of Dvarsater, WO 99/30652. These rejections are respectfully traversed.

The present invention is directed to a rectal insertion device and a method for treating disorders of the digestive track of a human or animal patient. Independent claims 1 and 2 are directed to the rectal insertion device, while independent claim 28 is directed to the method.

Independent claim 1 recites a combination of elements including "a second passageway which extends rearwardly in the device from a second forward opening in the forward end of the rearward section, said second forward opening in the operative position thereby acting to catch faeces discharged from the anal canal not caught in the first

passageway." In addition, independent claim 1 recites "wherein the first passageway communicates with the second passageway."

Independent claim 2 recites a combination of elements including "a rearward section having a forward end presenting a second forward opening intended to be extra-corporeally in use, said second forward opening being arranged rearwardly from the first opening, so that said second forward opening in the operative position thereby acts to catch faeces discharged from the anal canal not caught in the first passageway." In addition, independent claim 2 recites "wherein the first passageway communicates with the second passageway."

Independent claim 28 recites a combination of steps including "at least one time inserting a forward section of a device into the anal canal of the patient... said rearward section comprising a second passageway which extends rearwardly in the device from a second forward opening in the forward end of the rearward section so that said second forward opening in the operative position thereby acts to catch faeces discharged from the anal canal not caught in the first passageway." Independent claim 28 also recites "wherein the first passageway communicates with the second passageway."

With the above rectal insertion device and method of the present invention, it is possible to catch faeces discharged from the anal canal that are not caught in the first passageway. Applicant respectfully submits that the references relied on by the Examiner fail to teach or suggest the present invention as set forth in independent claims 1, 2 and 28.

At the outset, it is respectfully pointed out that the recitation "wherein the first passageway communicates with the second passageway" that has been added to independent claims 1, 2 and 28 was previously presented in dependent claim 10, which has been canceled. In the Examiner's Office Action, the Examiner indicated that dependent claim 10 was directed to allowable subject matter. In view of this, independent claims 1, 2 and 28 should be in condition for allowance for at least this reason.

With regard to the recitation of the second passageway that appears in independent claims 1, 2 and 28, the Examiner considers the Hegarty reference to anticipate this aspect of the present invention. However, the Hegarty reference is not related to a rectal insertion device, but to a urine collection device. Accordingly, the present invention is novel over Hegarty at least because independent claims 1 and 2 recite a rectal insertion device and independent claim 28 recites the step of "at least one time inserting a forward section of a device into the anal canal of a patient."

On the contrary, the Hegarty reference is concerned with a urine collection device in which the urine is collected solely through the conduit 1, whereas the outer jacket 6 is provided to conform with the contour of the surrounding tissue, and in which a partial vacuum is provided in order for the device to cling to the tissue surface in the region of the urethral orifice (see in particular the detailed description on page 5, line 8 to page 6, line 22).

Referring to page 2 of the Examiner's Office Action, the Examiner indicates that "if the prior art structure is capable of performing the intended use, then it meets the claim."

Applicant respectfully submits that independent claims 1, 2 and 28 now functionally define the presently claimed invention over the Hegarty reference. Specifically, the jacket 6 of Hegarty cannot be used to catch faeces discharged from the anal canal not caught in the first passageway, since the vacuum within the jacket 6 of Hegarty would provide suction through the end 9 of the jacket 6 and thereby block the opening 9 to prevent faeces discharged from the anal canal being caught in the second passageway of the jacket 6. In view of this, the structure of Hegarty cannot perform the function recited in the independent claims of the present invention.

With specific regard to independent claim 28, it is noted that the Examiner has not rejected 28 in view of the prior art. In view of this, it is believed that the Examiner is of the position that claim 28 is in condition for allowance. However, the Examiner discusses the Dvarsater reference with regard to claim 27 in order to modify Hegarty to insert the Hegarty device into the anal canal of a patient. To the extent the Examiner believes that method claim 28 is obvious over the combination of Hegarty in Dvarsater, Applicant provides the following comments.

In the Examiner's Office Action, the Examiner states "Hegarty's device is fully capable of being used as a rectal insertion device, [therefore] it is obvious to one with ordinary skill in the art to use the method of Dvarsater to insert Hegarty's device into the anal canal of user." Applicant is in complete disagreement with the Examiner's position. One having ordinary skill in the art would never use a urine collection device, which is specifically designed to catch urine from a female user and insert this device into the

rectum of a user in order to catch faeces as appears to be the position of the Examiner. Although there is some basis for the position that a device that is capable of performing a recited function anticipates a particular claim limitation, there is certainly no basis for the position that this same structure would be obvious to use in a particular manner. Claim 28 of the present invention is clearly directed to a method of treating disorders of the digestive tract and recites the step of "at least one time inserting a forward section of a device into the anal canal of the patient." The Hegarty reference clearly fails to disclose this step in independent claim 28 and there is absolutely no suggestion in the Dvarsater reference that would suggest one having ordinary skill in the art to use the Hegarty device in the manner suggested by the Examiner. In view of this, the Examiner's obviousness rejection is improper and should be withdrawn.

With regard to dependent claims 3-7, 9, 12-16, 18, 20-23, 26 and 27, Applicant respectfully submits that these claims are allowable due to their dependence upon allowable independent claims 1 and 2, as well as due to the additional recitations in these claims.

In view of the above amendments and remarks, Applicant submits that claims 1-7, 9, 12-16, 18, 20-23 and 26-28 clearly define the present invention over the references relied on by the Examiner. Accordingly, reconsideration and withdrawal of the Examiner's rejections under 35 U.S.C. §§ 102 and 103 are respectfully requested.

### **Allowable Subject Matter**

Claims 8, 10, 11, 17, 19, 24 and 25 stand objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicant greatly appreciates the indication of the allowable subject matter by the Examiner.

As mentioned above, the subject matter of dependent claim 10 has been added to independent claims 1, 2 and 28. In view of this, it is believed that independent claims 1, 2 and 28, as well as dependent claims 3-9 and 11-27 should now be in condition for allowance.

Favorable consideration and early allowance of the present application are respectfully requested.

### **CONCLUSION**

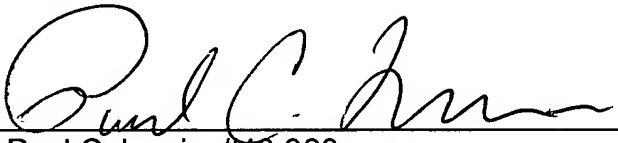
All the stated grounds of rejection have been properly traversed and/or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently pending rejections and that they be withdrawn.

It is believed that a full and complete response has been made to the Office Action, and that as such, the Examiner is respectfully requested to send the application to Issue.

In the event there are any matters remaining in this application, the Examiner is invited to contact Paul C. Lewis, Registration No. 43,368 at (703) 205-8000 in the Washington, D.C. area.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By   
Paul C. Lewis, #43,368

PCL/cl  
0104-0385P

P.O. Box 747  
Falls Church, VA 22040-0747  
(703) 205-8000